

# REFUNDED DENIED PCT NATIONAL DIVISION

PATÉNT RYAINTE JANCÉ DMSION Amylin Pharmaceuticals, Inc. 9360 Towne Centre Drive San Diego, CA 92121 USA

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2006 AUG -9 PH 4: 40

US PATENT & TRADEWARK OFFICE

August 3, 2006

U.S. First Class Mail

Attention: Refund Branch Mail Stop 16 Director of USPTO P.O. Box 1450 Alexandria, VA 22313-1450

Re: Request for refund to Deposit Account No. 010535

Dear Sir or Madam:

We are requesting a refund to our Deposit Account No. 010535 in the amount of \$2150.00 due to a claim calculation error on the part of the USPTO in USSN 10/559,595. Attached please find a copy of our Request for Corrected Filing Receipt filed on August 2, 2006. In addition, please find the Transmittal Letter and four (4) pages of claims filed on November 30, 2005 in support of our refund request. We authorized payment of a total of 27 claims with 3 independent claims; however, we were charged for a total of 50 claims with 8 independent claims incorrectly. Therefore, we respectfully request a refund to our deposit account at your earliest convenience.

Thank you in advance for your assistance in this matter.

Very truly yours,

AMYLIN PHARMACEUTICALS, INC.

Susan A. Mogavero

IP Supervisor

**Enclosures** 

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Appl. Serial No.:** 10/559,595

John ONG, et al

Filed:

Inventors:

November 30, 2005

Title: NOVEL METHODS AND COMPOSITIONS FOR ENHANCED TRANSMUCOSAL DELIVERY OF

PEPTIDES AND PROTEINS

Confirmation No.: Not Yet Assigned

TC/A.U.: Not Yet Assigned

Examiner: Not Yet Assigned

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## Certificate of Transmission Under 37 C.F.R. 1.8

I hereby certify that the following listed correspondence in the above-referenced application is being transmitted by facsimile to the Commissioner for Patents, Alexandria, VA to telephone number (571) 273-8300 on this 2nd day of August, 2006.

Document(s)

Susan A. Mogavero

No. of Pages

Request for corrected filing receipt
Filing Receipt
Corrected Filing Receipt
Transmittal Sheet as filed
Claims as filed

Total number of pages transmitted (including this page):

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Title: NOVEL METHODS AND COMPOSITIONS FOR ENHANCED TRANSMUCOSAL DELIVERY OF

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Examiner: Not Yet Assigned

## REQUEST FOR CORRETED FILING RECEIPT

Sir:

Applicant respectfully requests that the Filing Receipt for the above referenced patent application be corrected as follows:

**Total Claims: 27** 

Independent Claims: 3

A copy of the original Filing Receipt and Filing Receipt with corrections indicated is attached hereto. In addition, please find a copy of the Transmittal Letter with the correct fee calculation to the US DO/EO/US concerning a submission under 35 U.S.C. 371 along with Claims 1-27 as filed.

No fees are believed due for this request for correction to filing receipt. However, if a fee is due, the Commissioner is authorized to charge any fees associated with the present filing to Deposit Account No. 01-0535.

Please call the undersigned at the number listed below if there are any questions concerning this submission.

Respectfully submitted,

Susan J. Myers Fitch, Ph.D.

Reg. No. 55,477

AMYLIN PHARMACEUTICALS, INC. 9373 Towne Centre Drive San Diego, CA 92121 Phone 858.309-7695 Fax 858.552.1936

## 18528.912



### INITIED STATES PATENT AND TRADEMARK OFFICE

U501-UTL

UNITED STATES DEPARTMENT OF COMMERCE Status Palant and Trademas COMMISSIONER FOR PATENTS

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FILING OR 371 ARTUNIT FIL FEE REC'D ATTY. DOCKET NO (C) DATE 10/559,595 11/30/2005 1654 3100 0501-UTL-0

44638 ARNOLD & PORTER LLP (18528) 555 TWELFTH ST, NW WASHINGTON, DC 20004



**CONFIRMATION NO. 2750** 

FILING RECEIPT OC0000000186192081

Date Mailed: 04/27/2008

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

John Ong, San Marcos, CA; Robert Jennings, San Diego, CA; Gregg Stetsko, San Diego, CA;

Assignment For Published Patent Application

Amylin Pharmaceuticals, Inc., San Diego, CA

Amylin Docketing **Previously Docketed** 

Power of Attorney: The patent practitioners associated with Customer Number 44638.

Domostic Priority data as claimed by applicant

This application is a 371 of PCT/US04/17456 05/28/2004 which claims benefit of 60/474,233 05/30/2003

Foreign Applications

if Required, Foreign Filing License Granted: 04/25/2008

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, la US10/559.595

Projected Publication Date: 08/03/2008

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Non-Publication Request; No.

Docketed

MAY 03 2006

THE Date NA

ANYLIN PHARMACEUTICALS, INC. LEGAL DEPARTMENT



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CONFIRMATION NO. 2760

44838 ARNOLD & PORTER LLP (18528) 565 TWELFTH ST. NW WASHINGTON, DC 20004



FILING RECEIPT OC000000018819208

Date Mailed: 04/27/2008

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Projected Publication Date: 08/03/2008

Non-Publication Request: No

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Docketed The Date NIA MAY 0 3 2006

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| TRANSMITTAL LETTER TO THE UNITED STATES  |   |  | ATTORNEY'S DOCKET NUMBER 0501-UTL-0            |  |  |  |  |
|--|---|--|--|--|--|--|--|
| DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371                                     |   |  | U.S. APPLICATION NO. (H known, see 37 CFR 1.5) |  |  |  |  |
| INTERNA  | TIONAL APPLICATION NO.  | INTERNATIONAL FILING DATE                        | PRIORITY DATE CLAIMED                          |  |  |  |  |
| TITLE OF   | TILE OF INVENTION May 28, 2004 May 30, 2003   |  |  |  |  |  |  |
| Novel Methods and Compositions for Enhanced Transmucosal Delivery of Peptides and Proteins APPLICANT(S) FOR DO/EQUIS |   |  |  |  |  |  |  |
| John Ong, Gregg Stetsko, Robert Jennings   |   |  |  |  |  |  |  |
| _  | Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |  |  |  |  |  |  |
| 1 🖳  | This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.  |  |  |  |  |  |  |
| 2 📙  | This is a SECOND or SUBSEQUENT submission of Items concerning a submission under 35 U.S.C. 371.   |  |  |  |  |  |  |
| 3. 🗸   | This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.                                 |  |  |  |  |  |  |
| 4.   | The US has been elected (Article 31).   |  |  |  |  |  |  |
| 5. V   | A copy of the International Application   | n as Med (35 U.S.C. 371(c)(2))                   |  |  |  |  |  |
|  | a. Is attached hereto (required only if not communicated by the international Bureau).  |  |  |  |  |  |  |
|  | b has been communicated by the International Bureau.  |  |  |  |  |  |  |
|  | c. is not required, as the application was filed in the United States Receiving Office (RO/US).  An English tanguage translation of the International Application as filed (35 U.S.C. 371(c)(2)). |  |  |  |  |  |  |
| 6. 🗀   |   |  |  |  |  |  |  |
|  | a. is attached herato.  |  |  |  |  |  |  |
|  | b. has been previously submitted under 35 U.S.C. 164(d)(4).   |  |  |  |  |  |  |
| 7.   | Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))  |  |  |  |  |  |  |
|  | a. are attached hereto (required only if not communicated by the international Bureau).   |  |  |  |  |  |  |
|  | b. have been communicated by the International Bureau.  |  |  |  |  |  |  |
|  | c. have not been made; however, the time limit for making such amendments has NOT expired.  |  |  |  |  |  |  |
| _  | d. Aave not been made and will not be made.   |  |  |  |  |  |  |
| 8.   | An English tanguage translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).   |  |  |  |  |  |  |
| 9.   | An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).  |  |  |  |  |  |  |
| 10:  | An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 971(c)(5)).  |  |  |  |  |  |  |
| ltems  | s 11 to 20 below concern document(s) or information included:   |  |  |  |  |  |  |
| 11, 🔲  | An Information Disclosure Statement under 37 CFR 1.97 and 1.98.   |  |  |  |  |  |  |
| 12.  | An assignment document for recording. A separate cover sheat in compliance with 37 CFR 3.28 and 3.31 to included.   |  |  |  |  |  |  |
| 13.  | A preliminary amendment.  |  |  |  |  |  |  |
| 14.  | An Application Data Sheet under 37 CFR 1.76.  |  |  |  |  |  |  |
| 15.  | A substitute specification.   |  |  |  |  |  |  |
| 16.  | A power of attorney and/or change of address letter.  |  |  |  |  |  |  |
| 17. 🗹  | A computer-readable form of the sequence listing in accordance with PCT Rule 13/er.2 and 37 CFR 1.821- 1.825,   |  |  |  |  |  |  |
| 18.  | A second copy of the published International Application under 35 U.S.C. 154(d)(4).   |  |  |  |  |  |  |
| 19.  | A second copy of the English language   | u notissings landismetral erti for notislanari e | nder 35 U.S.C. 154(d)(4).                      |  |  |  |  |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application, Confidentially is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vizy depending upon the including case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief information Officer, U.S. Patent and Tradement Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Page 1 of 3

PTC-1390 (Rev. 07-2005)
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U.S. Patent and Thatemark Office; U.S. DEPARTMENT OF COMMERCE
ICATION NO. If known, see 37 CER 4 N. The preparative of the control number. U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

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| 20. Other kem  | s or Information:  | Sequence  <br>Compact D   | Specification - Marked-Up Ve<br>Listing on Compect Disk (2 c<br>isk Transmittal Letter<br>Under 37 C.F.R. 1.821(f)<br>I Card | rsion<br>oples) |                        |              |
| The followin   | g fees have been   | submitted   |  | <del></del>     | CALCULATIONS           | PTO USE ONLY |
| 21. Basic national fee (37 CFR 1.492(a))\$300  |  |   |  |                 | <sup>\$</sup> 300      | TO GOLL OILL |
| 22. 📝 Examinati  | on fee (37 CFR   | 1.492(c))   |  |                 | - 500                  | <del></del>  |
| If the written opinion p<br>by IPEA/US in<br>All other situations  | KNICO (OS O RELATIO  | s 200   |  |                 |                        |              |
| If the written opinion of<br>IPEA/US indic<br>Search fee (37 CFR 1<br>International Search R   | axes all claims s<br>.445(s)(2)) has t<br>Searching Author<br>Seport prepared t<br>Imunicated to the | \$ 100  |  |                 |                        |              |
| tor  | N DF 21 27 m   | d 21 a  |  |                 |                        |              |
| Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program fisting in an electronic medium) (37 CFR 1.492(j)).  The fee is \$256 for each additional 50 sheets of paper or fraction thereof.   |  |   |  |                 |                        |              |
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| Surcharge of \$130.00 after the date of comm   | for furnishing any<br>encoment of the  | \$  |  |                 |                        |              |
| CLAIMS NUMBER I  |  | FILED NUMBER EXTRA RATE   |  | 3               |                        |              |
| Total claims   | 27   | - 20 <b>=</b>   | 7  | x \$50          | \$ 350                 |              |
| Independent claims   | 3  | -3=   | 0  | x \$200         | \$ 0                   |              |
| MULTIPLE DEPENDE   | NT CLAIM(S) (if  | \$ 0  |  |                 |                        |              |
|  |  | \$ 950  |  |                 |                        |              |
| Applicant claims 8   | nal entity status  |   |  |                 |                        |              |
|  |  | \$ 950  |  |                 |                        |              |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).  |  |   |  |                 | \$                     |              |
|  |  | \$ 950  |  |                 |                        |              |
| ree for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property   |  |   |  |                 |                        |              |
| TOTAL FEES ENCLOSED = \$ 950   |  |   |  |                 |                        |              |
|  | ·  |   |  |                 | Amount to be refunded: | \$           |
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| d. Fees are to be charged to a credit card. WARNING: I be included on this form. Provide credit card inform  | Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. |  |  |  |  |  |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the international Application to pending status. |   |  |  |  |  |  |
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#### What is claimed is:

- 1. A pharmaceutical composition for transmucosal administration of an exendin or exendin analog, comprising an exendin or an exendin analog, a cationic polyamino acid, and a buffer; wherein at the pH of the composition the buffer does not cause precipitation of the cationic polyamino acid and has a mono-anionic or neutral net charge; and wherein the transmucosal absorption of the exendin or exendin analog is increased relative to the absorption of the exendin or exendin analog in the absence of the polyamino acid.
  - 2. The composition of claim 1, wherein the pH of the composition is between about pH 4.0 and about pH 6.0.
  - 3. The composition of claim 1, wherein the pH of the composition is between about pH 4.0 and pH 5.0.
- 4. The composition of claim 1, wherein the buffer is selected from the group consisting of acetic acid, \(\epsilon\)-aminocaproic acid or glutamic acid.
- 5. The composition of claim 1, wherein the buffer comprises glutamic acid.
- 6. The composition of claim 1, further comprising a tonicifying agent, a viscosity-increasing agent, a bioadhesive agent, a preservative, or any combination thereof.
- 7. The composition of claim 1, wherein the cationic polyamino acid comprises poly-histidine, poly-arginine, poly-lysine, or any combination thereof.
- 8. The composition of claim 7, wherein the cationic polyamino acid has an average molecule weight of between about 10 kDa and about 200 kDa.
- 9. The composition of claim 1, wherein the exendin or exendin analog is selected from at least one of the group consisting of exendin-3, exendin-4, exendin-4 acid,

exendin-4 (1-30), exendin-4 (1-30) amide, exendin-4 (1-28), exendin-4 (1-28) amide, <sup>14</sup>Leu, <sup>25</sup>Phe exendin-4 amide, and <sup>14</sup>Leu, <sup>25</sup>Phe exendin-4 (1-28) amide.

- 10. The composition of claim 1, wherein the exendin or exendin analog comprises exendin-4.
- 11. The composition of claim 1, wherein the exendin or exendin analog comprises exendin-3.
- 12. The composition of claim 1, wherein the exendin or exendin analog comprises at least one exendin selected from the group consisting of SEQ ID NOs: 9-39, 187 and 188.
- 13. The composition of claim 1, wherein the exendin or exendin analog comprises at least one exendin or exendin analog selected from the group consisting of SEQ ID NOs: 6-8 and 40-186.
- 14. The composition of claim 1, wherein the exendin or exendin analog comprises an amino acid sequence according to SEQ ID NO. 3.
- 15. The composition of claim 1, wherein the exendin or exendin analog comprises an amino acid sequence according to SEQ ID NO. 4.
- 16. The composition of claim 1, wherein the exendin or exendin analog comprises an amino acid sequence according to SEQ ID NO. 5.
- 17. The composition of claim 6, wherein the tonicifying agent is selected from the group consisting of sodium chloride, mannitol, sucrose, glucose and any combination thereof.
- 18. The composition of claim 6, wherein the viscosity-increasing agent is selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose of average molecular weight between about 10 and about 1,500 kDa, starch, gums, and any combination thereof.

- 19. The composition of claim 6, wherein the bioadhesive agent is selected from the group consisting of carbomer, polycarbophil and any combination thereof.
- 20. The composition of claim 6, wherein the preservative is selected from the group consisting of phenylethyl alcohol, methylparaben, ethylparaben, propylparaben, butylparaben, chlorbutanol, benzoic acid, sorbic acid, phenol, m-cresol, alcohol, and any combination thereof.
- 21. The composition of claim 1, wherein the absorption is increased at least 2 fold.
- 22. The composition of claim 1, wherein the absorption is increased at least 5 fold.
- 23. The composition of claim 1, wherein the absorption is increased at least 10 fold.
- 24. A pharmaceutical composition for transmucosal administration of an exendin or an exendin analog comprising about 0.10% to about 5.0% (w/v) of an exendin or an exendin analog; about 0.01% to about 1.0% (w/v) of a catioinic polyamino acid having a molecular weight between about 10 kDa and about 200 kDa; about 0.01% to about 10.0% (w/v) of a buffer, wherein at a pH of between about 4.0 and 5.0, the buffer does not cause precipitation of the cationic polyamino acid and the buffer has a mono-anionic or neutral net charge; and wherein the transmucosal adsorption of the exendin or exendin analog is increased relative to the adsorption of the exendin or exendin analog in the absence of the cationic polyamino acid.
  - 25. The composition of claim 24, wherein the exendin or exendin analog comprises exendin-4.

- 26. A method for transmucosal administration of an exendin or an exendin analog comprising contacting a mucosal surface with a composition comprising an exendin or an exendin analog, a cationic polyamino acid, and a buffer for a time sufficient for a therapeutically effective amount of said exendin or exendin analog to pass through the mucosal surface; wherein at the pH of the composition, the buffer does not cause precipitation of the cationic polyamino acid and the buffer has a mono-anionic or neutral net charge; and wherein the transmucosal adsorption of the exendin or exendin analog is increased relative to the absorption of the exendin or exendin analog in the absence of the cationic polyamino acid.
- 27. The method of claim 26, wherein the exendin or exendin analog comprises exendin-4.





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PAGE 61

Auy. Docker No. 0501-UTL

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl Scrial No.: 10/559,595

Inventore:

John ONG, et al November 30, 2005

TIB: NOVEL METHODS AND COMPOSITIONS FOR ENHANCED TRANSMUCOSAL DELIVERY OF PEPTIDES AND PROTEINS

Confirmation No.: Not Yet Assigned

TCALU: Not Yet Assigned Examiner: Not Yet Assigned

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